

PATENT
10/039,956
Docket 091/009c

REMARKS

This paper is responsive to the Office Action dated August 10, 2004, which is the second action on the merits of the application. The action has been made final.

Claims 1, 16, and 37-62 were previously pending, and all but claim 1 were under examination. Certain claims have now been amended, and claims 63-69 are newly added. The new claims also fall within the elected group. Accordingly, claims 1, 16, and 37-69 are pending; claims 16 and 37-69 are under examination.

Applicant acknowledges with gratitude withdrawal of the rejection under 35 USC § 112 ¶ 2, and the double patenting rejection with respect to copending application USSN 09/888,309. Other rejections are maintained, and are addressed below.

Reconsideration and allowance of the application is respectfully requested.

Amendments:

Entry of the amendments to the specification does not introduce new matter into the disclosure. The amendment to paragraph [0096] is taken directly from page 5, lines 20-23 of priority document 60/213,739. The amendment to paragraph [0099] is taken directly from page 15, lines 10-13 of the priority document. USSN 60/213,739 is incorporated into the present disclosure in its entirety by reference on page 1, lines 13-18 of the application as filed (paragraphs [0001] and [0002] of the application as published).

Entry of the claim amendments does not introduce new matter into the disclosure. Support for fibroblasts, mesenchymal cells, and hES-derived cells as feeders can be found in several places in the disclosure, such as paragraph [0106] of the Summary, and Example 12. The other new claims and claim amendments are supported *inter alia* by the claims as previously presented. Applicant reserves the right to reintroduce claims to additional subject matter described in the specification in this or any related application.

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Interview summary:

The undersigned is grateful to Examiners Thái-An N. Ton, Joseph T. Woitach, and Deborah Crouch for the courtesy of an interview at the Patent Office on Thursday, September 2, 2004. Possible claim amendments and arguments were discussed, along with possible declaration evidence regarding growing pPS cells in different media. The Examiners agreed that the present application would not be cited as prior art against subsequent applications by Geron Corporation et al. on culturing pPS cells in media not previously conditioned with feeder cells.

This Response incorporates amendments and remarks discussed during the interview.

Double Patenting

Certain claims in this application stand provisionally rejected for double patenting, with respect to certain claims of pending applications USSN 10/157,288 (docket 094/011); 10/087,473 (docket 090/003); 10/087,142 (docket 093/005); 10/313,739 (docket 132/002); and 10/189,276 (docket 098/003).

Applicant undertakes to address the double patenting issue appropriately upon determination that the claims in the present application and in USSN 10/087,142 (Geron docket 090/003) are otherwise patentable. A first Office Action on the merits has not yet been produced for the other cited applications. It is expected that the present application will be allowed at an earlier date.

Rejections under 35 USC § 112 ¶ 1:

The claims previously under examination stand rejected under the enablement requirement of § 112 ¶ 1. The Office Action indicates that the specification is enabling for methods of screening using pPS cells growing in a culture essentially free of feeder cells on an extracellular matrix in media conditioned by feeder cells, but not in other media. The Office Action cites an article by Lim et al (Proteomics 2:1187, 2002) as indicating that the feeder cells provide complex interaction with the embryonic stem cells comprising both membrane-bound and secreted factors that have not been identified. The Office Action further invites applicants to file an appropriate affidavit or declaration confirming that other media can support undifferentiated growth of pPS cells.

Applicant respectfully disagrees, for reasons stated previously. Federal Circuit case law clearly establishes that a patent applicant is not required to limit coverage to the working examples. Broader coverage is available under § 112 ¶ 1, providing there is no prior art that encroaches on the claimed scope outside the working examples. Now that applicant has demonstrated that human ES

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cells can be established and maintained in a feeder-free environment on an extracellular matrix, working alternatives can be identified and used by the skilled reader. By employing the culture test system and the marker assessment protocol provided in the specification (e.g., Examples 1-3), synthetically assembled media can be used and assessed to identify effective combinations of culture environment components.

Nevertheless, to expedite prosecution of the application, base claims 16 and 17 have now been amended to indicate that the undifferentiated stem cells are cultured in the absence of feeder cells *on an extracellular matrix in a medium conditioned by feeder cells*. Suitable feeder cells for conditioning the medium include fibroblasts, mesenchymal cells, and hES-derived cells (claims 63-65).

Withdrawal of this rejection is respectfully requested.

New claims 66-69 need not recite the conditions under which the hES cells are cultured, because the culturing of the cells is not actually part of the claimed procedure. The requirement of step (a) is that the undifferentiated hES cells used for screening be free of feeder cells. As such, they enter the method of claim 66 as a starting product. In order to meet the enablement requirements of § 112 ¶ 1, the specification need only teach at least one possible way of obtaining the product that is subsequently used for screening.

The enablement requirement is met if the description enables any mode of making and using the claimed invention.

Engel Industries, Inc. v. Lockformer Co., 20 USPQ2d 1300 (Fed. Cir. 1991).

Since the application demonstrates how hES cells can be grown in a feeder-free environment on an extracellular matrix in conditioned medium, the user may readily produce a population of hES cells *free of feeder cells*. The cells can then be used for screening as taught, for example, in paragraphs [0226] to [0228]. Depending on the objective, screening assays do not necessarily require the cells to be proliferating, and/or be maintained in an undifferentiated state.

Accordingly, claims 66-69 as currently presented meet all the requirements of 35 USC § 112 ¶ 1.

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Request for Further Interview

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested. In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests a further interview by telephone.

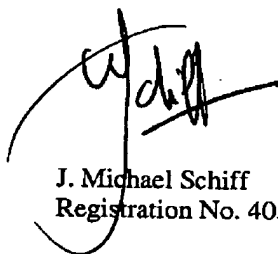
Fees Due

No fee is believed payable with respect to the amendments to the claims. Applicant has already paid for a total of 36 claims in this application.

This Amendment is accompanied by a Petition to change inventorship under 37 CFR § 1.48(b). The fee transmittal authorizes the Commissioner to charge the Deposit Account for the cost of the Petition.

Should the Patent Office determine that an extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



J. Michael Schiff
Registration No. 40,253

GERON CORPORATION
230 Constitution Drive
Menlo Park, CA 94025
Telephone: (650) 473-7715
Fax: (650) 473-8654

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